

COMMONWEALTH OF MASSACHUSETTS

MIDDLESEX, ss.

14

SUPERIOR COURT
CIVIL ACTION
NO. 03-5028-B

KARLA SAWYER & others¹

vs.

INDEVUS PHARMACEUTICALS, INC.²

**MEMORANDUM OF DECISION AND ORDER ON
DEFENDANT'S MOTION FOR SUMMARY JUDGMENT**

INTRODUCTION

The plaintiffs brought this action on December 11, 2003, against Indevus Pharmaceuticals, Inc. ("Indevus") seeking damages for alleged injuries caused by their use of the drug "Redux" (dexfenfluramine), a prescription drug used to manage obesity. The plaintiffs allege that Redux caused them to suffer Valvular Heart Disease (VHD). Counts I & II seek damages for breach of warranty, Count III for negligence, Count IV for negligent misrepresentation, and Count V for violating G.L. c. 93A.

Pursuant to Mass. R. Civ. P. 56(c), Indevus now moves for summary judgment on the ground that the plaintiffs' claims are barred by the relevant three and four year statutes of

¹ Linda Paul, Jeannie Rose, & Joyce Palomba

² F/k/a/ Interneuron Pharmaceuticals, Inc.

limitations.³ The plaintiffs oppose the motion, arguing that the statutes of limitations were tolled until they were diagnosed with VHID in late 2001/2002. For the reasons to follow, the defendant's motion will be **DENIED**.

BACKGROUND

This case is but one of thousands of similar cases nationwide arising out of heart damage allegedly suffered as a result of ingesting Redux (dexfenfluramine) and Pondimin⁴ (fenfluramine) (the "Diet Drugs" or "Diet Drug"). The following history of the Diet Drugs, related litigation (the "Diet Drug Litigation"), and the circumstances of this case is provided in as much detail as is necessary and relevant to deciding the defendant's motion.⁵

1. Redux Hits the Market

Indevus⁶ licensed the right to develop and promote Redux in the United States from Les Laboratoires Servier S.A., a French company. In 1994, Wyeth,⁷ the company marketing and promoting the related Fen-Phen combination, acquired Indevus' co-licensee. As part of the arrangement, Wyeth assumed responsibilities for developing and promoting Redux in the United

³ Counts I, II, III & IV are governed by three year statutes of limitations. See G.L. c. 260, § 2A; G.L. c. 106, § 2-318. Count V is governed by a four year statute of limitations. G.L. c. 260, § 5A.

⁴ Pondimin was commonly prescribed in combination with Phentermine. The combination is commonly referred to as "Fen-Phen." Phentermine is not part of the Diet Drug litigation.

⁵ The Multi District Litigation (MDL) Court which approved a related nationwide settlement provided an extremely thorough and detailed history of the Diet Drug Litigation which can be found at *Brown v. American Home Prods. Corp. (In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig.)*, Nos. MDL 1203, 99-20593, 2000 WL 1222042 (F.D. Pa. Aug. 28, 2000) (Bechtle, J.).

⁶ This court will refer to Interneuron Pharmaceuticals, Inc. as "Indevus" throughout this opinion.

⁷ At the time Wyeth was American Home Products, Corp.

States and the two companies entered into a co-promotional agreement. Indevus remained involved in its marketing, promotion and distribution, and sponsored the application for FDA approval which was granted in mid-1996. Production and robust sales followed shortly thereafter. *In re Diet Drugs*, 369 F.3d 293, 298 (3rd Cir. 2004) (by September 15, 1997 over four million people had taken Pondimin and two million had taken Redux).

2. *Valvular Heart Disease & the Diet Drugs*

Valvular Heart Disease manifests itself symptomatically as heart valve regurgitation, where the affected heart valve improperly permits blood to leak (or “regurgitate”) back into the chamber from which it was pumped. The Diet Drugs cause regurgitation by producing plaques that stick to the valve structure causing lesions thereon. Those lesions affect the normal function of the valve, ultimately causing regurgitation.

The regurgitation, if severe enough, can be detected through auscultation (listening to the heart through a stethoscope). However, even significant regurgitation may be silent on auscultation. On the other hand, the “gold standard” for detecting even minimal amounts of regurgitation is an echocardiogram. An echocardiogram is a noninvasive procedure whereby doctors use ultrasonic technology to obtain live pictures of the heart, much like the procedure used to view a fetus in the womb. Thus, regurgitation that may go undetected on auscultation would be detectable in an echocardiogram.

3. *Signs of Trouble Surface: Diet Drugs Withdrawn from the Market*

On July 8, 1997, doctors at the Mayo Clinic reported a possible association between the use of the Diet Drugs and VHD. The Mayo Clinic findings were issued in a press release and

were later formally published in the New England Journal of Medicine in late August of 1997.

As part of the press release, the Mayo Clinic included a section entitled "Information and Recommendations for People Taking Fenfluramine and Phentermine" which stated, *inter alia*:

If you are using fenfluramine and phentermine (fen-phen):

Contact your primary physician. Discuss these findings with your physician, and then ask him or her to help you weigh the benefits and risks of therapy.

Remain calm. More comprehensive study is needed to make a definitive statement about the association between [VHD] and [fen-phen].

Also on July 8, 1997, the FDA issued a public health advisory, and sent letters to 700,000 physicians requesting information about patients using the Diet Drugs. Based on the information received in response to that request, Redux and Pondimin were pulled from the market on September 15, 1997.

Wyeth promptly sent a "Dear Health Care Provider" letter on September 15, which characterized the association between VHD and the Diet Drugs as "preliminary," "difficult to evaluate," and "not derived from a thorough clinical study." The letter explained the decision to withdraw the drugs as "the most prudent course of action," and noted that "patients will be advised to contact their physicians." The letter did not indicate that the physician should consider or perform any specific tests or examinations. At the same time, Wyeth issued a press release and purchased advertisements in newspapers across the country. The advertisements were entitled: "An Important Message To Patients Who Have Used Pondimin® Or Redux™" and described a possible link between the Diet Drugs and VHD. Both the press release and the advertisement concluded by stating, "patients who have used either [Pondimin or Redux] should contact their physicians."

At the time of the withdrawal, neither the pharmaceutical companies nor the government notified Diet Drug users that an echocardiogram was necessary to diagnose or discover VHD. Diet Drug users were told only to consult their physicians.

4. Media Coverage & Public Notice

There can be little doubt that the potential link between the Diet Drugs and heart disease and the Diet Drug withdrawal was one of the biggest news stories of 1997. Local and national media outlets extensively covered the July 8 announcement, including newspapers and television newscasts. For example, *The New York Times* and *USA Today* both ran four-page articles bearing the headlines “2 Popular Diet Pills Linked to Problems with Heart Valves” and “Diet Drug Patients Get Heart Warning” respectively. Gina Kolata, 2 popular Diet Pills Linked to Problems with Heart Valves, N.Y. Times, July 9, 1997, at A1; Nancy Hellmich, Diet Drug Patients Get Heart Warning, USA Today, July 9, 1997, at 1A. Local and Regional papers across the nation and New England, such as *The Boston Herald* and *The Boston Globe*, featured front-page reports on the Mayo Clinic announcement. See, e.g., Michael Lasalandra, Study Links Diet Pill Fen-Phen to Heart Problems, Boston Herald, July 9, 1997, at 1; Dolores Kong, Blend of Diet Drugs Tied to Heart Disease, Boston Globe, July 9, 1997, at A1.

The September 15 withdrawal of the Diet Drugs received similar headline coverage. Both Tom Brokaw on “NBC Nightly News” and Dan Rather on “CBS Evening News” led the evening newscasts with stories covering the withdrawal. NBC Nightly News (NBC Television Broadcast, September 15, 1997); CBS Evening News (CBS Television Broadcast, September 15, 1997). *The New York Times* and the *Washington Post* also ran front-page headline stories of the

withdrawal. Gina Kolata, 2 Top Diet Drugs Are Recalled Amid Reports of Heart Defects, N.Y. Times, September 16, 1997, at A1; John Schwartz, 2 Diet Drugs Are Pulled off Market, Washington Post, September 16, 1997, at A1. Similar stories saturated local and regional newspapers. E.g., Norma Wagner, Drug Seller Pulls Its Diet Pills; FDA Says Review Suggests Drugs Are Not Heart-Healthy, Salt Lake Tribune, September 16, 1997, at A1; Richard A. Knox, 2 Diet Drugs Pulled As Fears Grow, Boston Globe, September 16, 1997, at A1; Michael Lasalandra, Docs Urge Former Fen/Phen Takers to Get Thorough Checkups, Boston Herald, September 17, 1997, at 7.

In short, it was virtually impossible to escape the widespread coverage of the issue. This court recognizes that a reasonable Pondimin or Redux user should have, at minimum, been aware of the controversy and the possibility that he or she was at risk for heart disease. What requires closer attention, however, is the actual content of that coverage and the precise message, if any, a Diet Drug user should have taken therefrom.

The preliminary media reports in July of 1997 indicated that researchers had uncovered a potential link between the Diet Drugs and VHD. For example, the initial press release from the Mayo Clinic described the health risks possibly associated with the use of Diet Drugs, and newspaper and news broadcast coverage of the report provided details of the Mayo Clinic's findings, which included abnormal echocardiogram findings. Subsequent reports focused on the potential link. See, e.g., Chris Tomlinson, Diet-Drug Mix May be Deadly FDA Warns; "Fen-Phen" Linked to Heart, Lung Damage, San Francisco Examiner, July 9, 1997, at A1; Terence Monmaney, Fen-Phen May Cause Damage to Heart Valves, Los Angeles Times, July 9, 1997, at A1. Similarly, a New York news broadcast warned: "If you or someone you know are taking

Fen-Phen to lose weight, this is a story you must hear. Researchers say the pills could put your health at risk.” 2 News This Morning (WCBS-TV Television Broadcast, July 9, 1997). The media also began to report that Diet Drug users should consult their physicians. An article in *The Boston Globe*, for example, urged users to “see a doctor and get a physical exam,” as the Diet Drugs “were pulled from the market because extended use for six months or more ha[d] been linked to potentially deadly heart valve damage.” Exams Urged For All Users of Fen-Phen, Redux, *Boston Globe*, November 14, 1997, at A3. See also Nancy McVicar and Glenn Singer, Study: Diet Drugs May be Associated With Heart Disease “Fen-Phen” Could Damage Valves, Doctors Conclude, *Sun-Sentinel*, July 9, 1997, at 1A (providing readers with the typical symptoms of heart valve problems and recommending that patients using the medication “[d]iscuss the findings with [their] doctor[s]”).

The media attention surrounding the Diet Drug withdrawal in September of 1997 was accompanied by widespread warnings to stop taking them and to consult a physician. The Wyeth, Indevus and FDA press releases discussed abnormal echocardiogram findings in the patients, but did not advise the users to have an echocardiogram performed; rather, the releases uniformly advised Diet Drug users to “contact their doctors.” See, e.g., Press Release, Food and Drug Administration, FDA Announces Withdrawal of Fenfluramine and Dexfenfluramine (September 15, 1997) (specifically urging users to stop taking the drugs and to contact their physicians). Similarly, newspapers nationwide conveyed the same warnings and advice. E.g., Tara Meyer, Diet Drug Users Are Told to See Doctors; Advice Goes for Those Feeling Fine, *Boston Herald*, November 14, 1997, at 3; Exams Urged for All Users of Fen-Phen, Redux, *Boston Globe*, November 14, 1997, at A3; Marlene Cimon, 2 Diet Drugs Tied to Heart

Problems Taken Off the Market, Los Angeles Times, September 16, 1997, at A1 (discussing the removal and advising users to “immediately stop taking the pills . . . [and] [s]ee a doctor”); Lauran Neergaard, Recall Spurs Dieters to Seek Heart Test, Buffalo News, September 25, 1997, at A8 (“immediately stop taking the drugs and see a doctor”).

As the general public was receiving information concerning Diet Drugs and VHD, so too was the medical community.⁸ The pharmaceutical companies themselves advised physicians of the Mayo clinic findings and FDA data. Physicians were notified that Diet Drug users had been advised to contact them. Neither Diet Drug users or their treating physicians, however, were advised that an echocardiogram should have been performed. To the contrary, the government, authoritative medical associations and the Diet Drug manufacturers themselves uniformly advised that standard examinations should be performed to determine whether further echocardiogram testing was called for. For example, the Department of Health and Human Services recommended to physicians that they take a medical history of Diet Drug patients and perform a cardiac exam—only performing an echocardiogram if the initial exam indicated VHD. The advice from all of the medical and scientific communities to physicians in this regard (as it appears in the record presently before the court) was uniform—order an echocardiogram only when cardiac examination/auscultation indicates detectable VHD. Indeed, Wyeth sent a letter to Secretary of Health and Human Services, Donna Shalala, discouraging her from recommending routine echocardiograms for Diet Drug users. Specifically, Wyeth advised her that “such a

⁸ As will be discussed below, the relevance of these notices to the current motion is dubious. None of the plaintiffs were physicians and should not reasonably be expected to have known or discovered (let alone, understood) the contents of technical bulletins issued to the medical community. In any event, as noted, it appears undisputed that the protocol for examining asymptomatic Diet Drug users did not include echocardiogram examination.

recommendation would be inconsistent with a recommendation recently issued by the American College of Cardiology as well as with what we understand to be the weight of expert opinion in the cardiology community.”

In short, when the drugs were removed from the market in September of 1997 and thereafter, Diet Drug users were notified of the potential association between the Diet Drugs and heart disease and were directed to consult with their physicians. Importantly, however, neither Diet Drug users nor their physicians were advised that an echocardiogram should be performed as a matter of course. Despite the eight hundred and sixty one exhibits offered by Indevus in support of its motion—most of which are media reports, it has not brought to this court’s attention a single public report that would have put Diet Drug users on notice that an echocardiogram was necessary to diagnose Diet Drug induced heart disease.⁹

5. *The Lawsuits Begin*

Almost immediately after the Diet Drugs were withdrawn from the market, thousands of lawsuits were filed against Wyeth and Indevus. *In re Diet Drugs*, 2004 WL 1152824 at *3 (eighteen thousand lawsuits filed; one hundred putative class actions). Litigation was consolidated in state courts throughout the nation, including Massachusetts. In the federal courts, the Judicial Panel on Multidistrict Litigation (MDL) created a multidistrict litigation docket in the United States District for the Eastern District of Pennsylvania in December, 1997, presided

⁹ Judge Bechtle characterized the publicity surrounding the withdrawal as an “unprecedented amount of publicity which effectively warned Diet Drug users that they may have developed valvular lesions which could be detected through non-invasive echocardiograms.” *Brown*, 2000 WL 1222042, at *18. With due respect for that Court’s characterization, Indevus has not directed this court to anything in the record of *this* case that would lead to the same conclusion.

over by Judge Louis Bechtle.

Negotiations between Wyeth and putative class members commenced, and in November of 1999, a tentative global settlement agreement (the "Agreement") was reached and conditionally approved by the MDL court. The Agreement subdivides the class, defined as all person in the U.S. who ingested Redux or Pondimin, based on the length of use of the Diet Drugs and severity of injury, if any, diagnosed before September 30, 1999. During the course of settlement negotiations, each subclass was represented by independent counsel to advance and protect its interests. There was, however, no subclass with independent representation defined as asymptomatic Diet Drug users as of September 30, 1999.

Indevus was/is not a party to the Agreement.

6. *The MDL Court Approves A Nationwide Class Action Settlement with Wyeth*

Wyeth and the class representatives moved jointly to approve the settlement. On August 28, 2000, Judge Bechtle certified the class and approved the Agreement. *Brown v. American Home Prods. Corp. (In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig.)*, Nos. MDL 1203, 99-20593, 2000 WL 1222042, Memorandum and Pretrial Order No. 1415, (E.D. Pa. Aug. 28, 2000) (hereinafter "*Brown*"). The Agreement became effective on January 3, 2002, the date of Final Judicial Approval.

A. *The Agreement*

The Agreement was designed to shield Wyeth against excessive liability while simultaneously preserving class members' rights to compensation for their injuries—either through the newly created settlement fund or through claims in the tort system. See generally, *In*

re Diet Drugs, 369 F.3d at 296-300. Under the terms of the Agreement, Wyeth agreed to pay up to approximately \$3.75 billion into a settlement trust to provide benefits to class members in exchange for a release of all settled claims. Importantly, the Agreement was structured so as to eliminate an ‘all or nothing’ choice for class members with respect to participation in the settlement; the Agreement provided several avenues through which class members could “opt-out” and pursue their claims in the tort system, even after the Agreement became effective.

The opt-out provisions worked as follows. All class members could exercise an “initial opt-out right,” through which they could remove themselves entirely from the class and prosecute their claims without effect from the Agreement. The deadline to exercise this right was March 30, 2000. Those who chose not to exercise the initial opt-out are bound by the terms of the Agreement. The Agreement provides for a screening period, during which class members could receive an echocardiogram.¹⁰ Importantly, the Agreement protects class members’ rights to pursue claims in the tort system if they discover their heart conditions during the screening period—a time when their claims might otherwise be barred by local statutes of limitations. If diagnosed with VHD during the screening period, class members could elect either to receive benefits from the settlement fund or to exercise an “intermediate” or “back-end” opt-out through which they could pursue their claims in the tort system.

For a class member diagnosed with “mild mitral regurgitation”¹¹ during the screening period, settlement benefits are available in the event that the condition progresses to serious

¹⁰ The Screening Period commenced on January 3, 2002, and ran for twelve months terminating on January 3, 2003. It could be extended for an additional six months for cause shown.

¹¹ A “completely asymptomatic condition” requiring no treatment. *Brown*, 2000 WL 1222042, at *10.

levels by the year 2015. In the alternative, he/she may exercise the “back-end opt-out.” Under the “back-end opt-out,” class members may not pursue claims for consumer fraud, exemplary, punitive, or multiple damages and Wyeth cannot assert, *inter alia*, any statute of limitations defense.

For class members diagnosed with “FDA Positive”¹² levels of VHD during the screening period, the member has a similar choice of electing benefits from the settlement or opting out to pursue claims in the tort system. Under the “intermediate opt-out,” class members similarly are entitled only to pursue compensatory damages and Wyeth is precluded from asserting a statute of limitations defense.

In short, the Agreement was structured in such a way as to remove statutes of limitations as an obstacle to recovering compensatory damages for class members who either (a) discover their conditions before January 3, 2003 but after the applicable state statute of limitations may have expired (like the plaintiffs), or (b) have conditions which progress over time to a compensable level.

The Agreement was also designed to limit its preclusive effects against both parties, except as contemplated by the parties and explicitly stated in the Agreement itself. See *In re Diet Drugs*, 369 F.3d at 308-310. The Agreement contained several provisions prohibiting the parties from using the Agreement or statements and/or proceedings related to its negotiation and approval in contexts other than its execution and enforcement. Notably, Section VIII.F.3 of the Agreement provides:

The Parties to the Settlement ... shall not seek to introduce and/or offer the terms of

¹² The clinical term characterizing “moderate” or “severe” levels of mitral valve regurgitation.

the Settlement Agreement, any statement, transaction or proceeding in connection with the negotiation, execution or implementation of this Settlement Agreement, any statements in the notice documents appended to this Settlement Agreement, stipulations, agreements, or admissions made or entered into in connection with the fairness hearing or *any finding of fact or conclusion of law made by the Trial Court*, or otherwise rely on the terms of this Settlement, in any judicial proceeding, except insofar as it is necessary to enforce the terms of the Settlement. (emphasis added).

Section VIII.F.4 provides:

Neither this Agreement nor ... any statement, transaction or proceeding in connection with the negotiation, execution or implementation of this agreement, is intended to be or shall be construed as or deemed to be evidence of ... an admission by ... members of the settlement class of any lack of merit in their claims, and *no such statement, transaction, or proceeding shall be admissible in evidence for any such purpose except for purposes of obtaining approval of this Settlement Agreement* in this or any other proceeding. (emphasis added).

B. The Settlement Approval Process - Notice

As part of the settlement approval process, an extensive notice program for prospective class members was initiated.¹³ The notice program had two parts. The first was designed to inform putative class members of the health risks associated with the Diet Drugs, class members' legal rights, and that there was a proposed settlement. This part of the notice program was implemented through large scale media advertising, including television and newspaper commercials as well as through dissemination of materials to pharmacies and health care providers. This first part of the notice program also directed Diet Drug users to obtain an official "notice package"—the second part of the notice program.

The "notice package" was sent directly to more than 200,000 known Diet Drug users and could be obtained by other Diet Drug users through an advertised website and toll free phone

¹³ Judge Bechtel described it as "an elaborate and extensive plan of notice." *Brown*, 2000 WL 1222042, at *35.

number. The “notice package” contained two components. The first, which was approved by the MDL Court, was a brochure that provided “the background of the Diet Drug Litigation and the Settlement Agreement in a way that would be read and understood by all class members. . . it was written in plain English and contained a number of pictures, charts and graphs.” *Brown*, 2000 WL 1222042, at *37. The brochure did not inform Diet Drug users of the possibility that non-settling parties could use the negotiations, the hearings, or the Agreement against class members in the future.

The second component of the “notice package” was the Official Court Notice, which “contained a detailed description of the Settlement Agreement, typeset in the manner traditionally used to provide legal notice.” *Id.* Under the section entitled, “Definition of ‘Released Parties’—By participating in this settlement agreement, who am I agreeing to release from existing or future lawsuits regarding my use of Pondimin and/or Redux?”, Indevus is specifically listed as a “non-released” party. In addition, the notice provides: **“The rights of Class Members to pursue legal claims against Non-Settling Defendants is not affected by this Settlement Agreement...”** (Emphasis added).

C. MDL Court Approval of the Settlement Agreement

The MDL Court held a comprehensive evidentiary fairness hearing to aid in determining whether to certify the class and approve the settlement under Fed. R. Civ. P. 23. In order to approve the Agreement, the Court had to find that it sufficiently protected the rights of all putative class members—*i.e.*, that there were no disabling conflicts of interest between subgroups within the class. Specifically, it was critical that there was no “futures” problem as identified by

the United States Supreme Court in *Amchem Products, Inc. v. Windsor*, 521 U.S. 591 (1997), such as a conflict between those class members currently injured and those whose injuries may be latent. *Brown*, 2000 WL 1222042 at *45-49. The “objectors” to the settlement were afforded “a full and fair opportunity to offer all of the evidence that they wished to tender to the court concerning” the proposed Agreement. *Id.* at *6. There were fewer than thirty objectors, none of whom presented any medical or scientific evidence to counter the proponents’ latency claims. *Id.*¹⁴

Judge Bechtle noted that all of the literature and medical testimony before him indicated that valvular lesions (the root cause of Diet Drug induced VHD/regurgitation) are not latent, that is, they occur at or shortly after the time of Diet Drug ingestion. *Brown*, 2000 WL 1222042 at *18 & 46-47. The Court specifically held that Diet Drug induced VHD is clinically detectable “shortly after” cessation of Diet Drug use. *Id.* at *46. However, the Court also noted that it was “generally accepted that VHD . . . is potentially progressive.” *Id.* at *10.

In light of these findings, Judge Bechtle first acknowledged the substantial statute of limitations obstacle that could face many potential class members who tried to pursue their claims in state courts. The Court specifically noted that it was “beneficial for diet drug recipients to obtain appropriate legal protections such that they have a viable claim for relief when, as, and if, they discover they have either FDA positive levels of regurgitation or that they have serious VHD” because of “vagaries in the law governing recovery for potentially progressive injuries” and the potentially preclusive effects those vagaries might have on “damage claims of individuals

¹⁴ The plaintiffs in this case present the affidavit of Dr. James Oury, who avers that he informed class counsel in *Brown* of his opinion that VHD was latent but that, for reasons unknown to him, he was not called to testify at the fairness hearing.

who are not presently suffering from serious diet-drug induced VHD.” *Id.* at *18-*19. After the Court’s analysis, it concluded that the Agreement provided sufficient protection for all class members’ rights.

First, all class members screened by echocardiogram within the applicable screening period would know whether they had been affected by the Diet Drugs, because, as the Court held, lesions were not latent and were immediately detectable by an echocardiogram. Therefore, there was no risk of a subclass being shut-out from settlement benefits because of a latent onset of valvular lesions. Moreover, for those who were asymptomatic or whose conditions worsened over time, their rights were protected by the intermediate and back-end opt-out provisions as well as provisions entitling them to enhanced benefits when and if symptoms worsened.

That the Court and the Agreement anticipated latent or progressive symptoms is manifest in the Agreement itself. Class members merely needed to demonstrate a relatively mild level of VHD by January 3, 2003, and had until 2015 to assert their claims—whenever their conditions progressed to compensable levels. Moreover, subclasses 1(a) and 1(b) included Diet Drug users who were not diagnosed as having FDA positive levels of VHD by September 30, 1999. Both subclasses were entitled to benefits under the Agreement when and if their conditions reached a certain severity. It is clear, then, that the Agreement anticipated that regurgitation/VHD may be either symptomatically latent or progressive in nature. Indeed, class counsel’s Memorandum in Support of Final Settlement Approval, which is part of the record in the current case, indicates as much. In arguing that there was no futures problem, class counsel stated:

The current settlement affords the required option by way of the intermediate and back-end opt-out provisions. Moreover, the settlement goes a step further by providing medical monitoring to inform persons of their injury status. Those class

members who pass through the medical monitoring program and learn they have a clinically significant injury as defined by the FDA criteria will have the right to opt out of the settlement and take their claims to court. If, during the ensuing fifteen years, a previously uncompensated class member has an injury that progresses to a higher level of valvulopathy, the individual has one more chance to opt out and pursue individual litigation if he or she does not like the settlement matrix benefits.

Thus, agreeing with class counsel and finding that the Agreement adequately protected against a fatal *Amchem*-like “futures” problem, Judge Bechtle approved the Agreement.

7. *The Plaintiffs*

There are four plaintiffs in the current action: Karla Sawyer, Linda Paul, Jeannie Rose, and Joyce Palomba. Sawyer, Paul and Rose all ingested Redux in 1996 and 1997. Palomba ingested Redux in 1996. In late 1997, Sawyer’s physician discontinued her use of Rexux and referred her for an echocardiogram. She was told that the echocardiogram was normal and that she had nothing to worry about. Each year from 1996 through 2002, the plaintiffs visited physicians for yearly physicals, regular checkups, and treatment of minor ailments. All of their physicians examined their hearts through auscultation. None of the plaintiffs was told that those examinations were irregular, that there was any indication of a heart murmur or other cardiac abnormality, or that she had any other problem associated with Redux. They all felt in good health and had no indications of heart problems. During that time, neither Paul, Rose nor Palomba was advised to have an echocardiogram. If so advised, they all would have consented to the procedure.

In November of 2001 and December, May and June of 2002, Rose, Sawyer, Paul and Palomba respectively, had echocardiograms performed. It was at these times that the plaintiffs first learned they had VHD.

8. *Procedural and Circumstantial Posture of This Case*

This case was brought solely against Indevus, a Delaware Corporation with its principal place of business in Lexington, Massachusetts. Subsequent to the Agreement being approved, many suits have been filed across the Nation in state courts against Wyeth under the Intermediate and/or Back-end opt-out provisions. Many of these plaintiffs apparently believe that state courts provide a more favorable forum for their claims, and have allegedly attempted to avoid removal to the MDL Court by joining non-diverse defendants alongside Wyeth, thus defeating diversity jurisdiction in the federal courts. Wyeth maintains that it has successfully overcome many such attempts by asserting the doctrine of fraudulent joinder.

Under the doctrine of fraudulent joinder, a plaintiff may not prevent removal by making a claim against a non-diverse defendant when there is no reasonable basis in fact or colorable ground supporting that claim. Thus, where claims against the non-diverse defendant are barred by the statute of limitations, the federal court's jurisdiction over claims against the diverse defendant will not cease. In related Diet Drug Litigation, the MDL Court on several occasions has retained jurisdiction over cases where the state statute of limitations would preclude claims against fraudulently joined non-diverse physicians or other defendants. See, e.g., *French v. Wyeth*, MDL No. 1203, Civil Action No. 03-20206 (E.D. Pa. Feb. 16, 2004); *Alexander v. Wyeth*, MDL No. 1203, Civil Action No. 03-20206 (E.D. Pa. Jan. 29, 2004); *Ferrell v. Wyeth*, MDL No. 1203, Civil Action No. 03-20094 (E.D. Pa. Sept. 5, 2003).

Plaintiffs from around the country are allegedly now testing this strategy in Massachusetts. See, e.g., *Anderson v. Indevus Pharmaceuticals, Inc.*, Civil No. 04-911

(Middlesex Sup. Ct). Wyeth has removed those cases, in which it is a named defendant, to the United States District Court for the District of Massachusetts, and will assert that the plaintiffs have fraudulently joined Indevus based on the expiration of the relevant statutes of limitations and that the cases should be transferred to the MDL Court. The current plaintiffs have brought this case in the Massachusetts Superior Court, so that they can obtain a ruling from a Massachusetts Court on whether their claims against Indevus are barred by the Massachusetts statutes of limitations and therefore whether the removed cases should be remanded to the Superior Court.

This court recognizes the larger implications of the following decision and its possible relevance to the many¹⁵ additional cases waiting in the balance. That circumstance will play no role in the following decision. The plaintiffs and the defendant have a right, which this court will fully honor, to have this motion decided on the merits.

DISCUSSION

1. Issues for Summary Judgment

Indevus argues that the applicable statutes of limitations bar the plaintiffs' claims. Specifically, it argues that the plaintiffs, as a result of the intense media attention on or about September of 1997, were on inquiry notice that they potentially had VHD and, as a matter of law, should have discovered their conditions at or about that time. The plaintiffs argue that the discovery rule saves their claims, because they did not know, nor should they have been expected to know, that they had VHD until echocardiograms in 2001 and 2002 resulted in positive

¹⁵ Wyeth, who has filed an *amicus* brief, claims that plaintiffs' counsel has indicated its intent to bring cases on behalf of 4,597 plaintiffs—in addition to the already 2,368 Diet Drug plaintiffs with cases pending—if they are successful in defeating the current motion.